

CLAIMS

1. A method of diagnosing cancer in a patient comprising assaying a sample of biological fluid from a patient for the presence or absence of survivin, wherein the presence of survivin in the sample indicates that the patient has cancer.

2. The method of claim 1, wherein the biological fluid is urine or blood serum.

3. The method of claim 1, wherein the cancer is any cancer invading the genitourinary tract.

4. The method for claim 3, wherein the genitourinary tract cancer is bladder or prostate cancer.

5. The method of claim 4, wherein the bladder or prostate cancer is graded as a CIS.

6. The method of claim 4, wherein the bladder or prostate cancer is any grade or any stage.

7. The method of claim 1, wherein survivin is detected using an agent selected from the group consisting of antibodies that bind survivin, survivin binding partners, and nucleic acids that hybridize to a nucleic acid encoding survivin.

8. The method of claim 7, wherein the agent is tagged with a label.

9. The method of claim 8, wherein the label is a radioactive label, a fluorescent label, an enzyme, or a chemiluminescent tag.

10. The method of claim 1, wherein survivin is detected by an immunoassay.

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11. The method of claim 10, wherein the immunoassay is an enzyme linked immunosorbent assay or radioimmunoassay.

12. The method of claim 10, wherein the immunoassay comprises immunoblotting, immunodiffusion, immunoelectrophoresis, or immunoprecipitation.

13. The method of claim 1, wherein survivin is detected by dot blotting.

14. The method of claim 13, wherein dot blotting comprises using a Bio-Dot SF module.

15. The method of claim 1, wherein survivin is detected by nucleic acid hybridization.

16. The method of claim 15, wherein the nucleic acid hybridization is RT-PCR or Northern blot analysis.

17. A kit for diagnosis, prognosis, or monitoring cancer, comprising a container for collecting biological fluid from a patient and an agent that detects the presence of survivin in the biological fluid.

18. The kit of claim 17, wherein the agent is selected from the group consisting of antibodies that bind survivin, survivin binding partners, and nucleic acids that hybridize to the nucleic acid encoding survivin.

19. The kit of claim 18, wherein the agent is tagged with a label.

20. The kit of claim 18, wherein the label is a radioactive label, a fluorescent label, an enzyme, or a chemiluminescent tag.

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21. The kit of claim 17, wherein the agent is packaged in an aqueous medium or in lyophilized form.

22. The kit of claim 17, further comprising a means to analyze the presence of survivin.

23. The kit of claim 17, wherein the cancer is bladder or prostate cancer.

24. The kit of claim 17, wherein the biological fluid is urine or blood serum.

25. A method of determining the grade of a cancer in a patient comprising quantitating the amount of survivin in the sample of biological fluid from a patient and comparing the amount of survivin in the sample with the amount of survivin in control samples to determine the grade of the cancer.

26. A method of determining the stage of a cancer in a patient comprising quantitating the amount of survivin in the sample of biological fluid from a patient and comparing the amount of survivin in the sample with the amount of survivin in control samples to determine the stage of the cancer.

27. A method of monitoring cancer in a patient comprising quantitating the amount of survivin in the sample of biological fluid from a patient to determine the grade of the cancer.

28. The method of claim 1, wherein the biological fluid is selected from the group consisting of prostatic fluid, seminal fluid, whole blood, serum, urine, breast biopsy fluid, gastrointestinal fluid, and vaginal fluid.

29. The method of claim 1, wherein the cancer is any cancer that expresses survivin.

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30. The method of claim 1, wherein the cancer is selected from the group consisting of neuroblastoma, breast cancer, lung cancer, bladder cancer, colorectal cancer, pancreatic cancer, genitourinary tract cancer, prostate cancer, renal cancer, and bladder cancer.

31. The method of claim 1, wherein the cancer is new onset cancer or recurrent cancer.

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